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EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/20/2003

40

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/360,685

Applicant(s)  
Covacci et al.

Examiner  
S. Devi, Ph.D.

Art Unit  
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 26, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 40, 41, 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 72, 75, 76, 78, 80, 91, 93, 123-128, 130 and 139 is/are pending in the application.
- 4a) Of the above, claim(s) 121 and 122 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40 and 41 is/are allowed.
- 6) ☒ Claim(s) 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 72, 75, 76, 78, 80-91, 93, 123-128, 130 and 139 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 39.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence search reports (5).

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### **Request for Continued Examination**

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 02/26/03 (paper no. 37) has been entered.

### **Applicants' Amendment**

2) Acknowledgment is made of Applicants' amendment filed 02/26/03 (paper no. 38) in response to the final Office Action mailed 11/01/02 (paper no. 35). With these, Applicants have amended the specification.

### **Status of Claims**

3) Claims 92, 94-120, 129 and 131-138 have been canceled via the amendment filed 02/26/03. Claims 45, 54, 56, 57, 59, 62, 63, 70, 75, 78, 80 and 81 have been amended via the amendment filed 02/26/03.

Claims 40, 41, 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 72, 75, 76, 78, 80-91, 93, 121-128, 130 and 139 are pending.

Upon further consideration, claims 81, 84-91, 93, 123-128, 130 and 139, previously withdrawn from examination, have been rejoined with the elected invention and examined.

Claims 121 and 122 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 40, 41, 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 72, 75, 76, 78, 80-91, 93, 123-128, 130 and 139 are under examination.

### **Information Disclosure Statement**

4) Acknowledgment is made of Applicants' information disclosure statement filed 02/26/03 (paper no. 39). The information referred to therein has been considered and a signed copy of the same is attached to this Office Action (paper no. 40).

### **Prior Citation of Title 35 Sections**

5) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

**Prior Citation of References**

6) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

**Rejection(s) Withdrawn**

7) The rejection of claims 45, 47, 48, 54, 56, 57, 59, 62, 63, 68, 70, 75, 76, 78, 80, 82, 83, 124 and 125 made in paragraph 17 of the Office Action mailed 02/28/02 (paper no. 28) and paragraph 25 of the Office Action mailed 11/01/02 (paper no. 35) or maintained in paragraph 23 of the Office Action mailed 11/01/02 (paper no. 35) under 35 U.S.C. § 112, first paragraph, as being non-enabled, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

8) The rejection of claims 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 75, 76, 78 and 80 made in paragraph 24 of the Office Action mailed 11/01/02 (paper no. 35) under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

9) The rejection of claims 45, 54, 57, 62, 63, 70 and 78 made in paragraph 26(a) of the Office Action mailed 11/01/02 (paper no. 35) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

10) The rejection of claims 47, 68, 56, 59 and 80 made in paragraph 26(b) of the Office Action mailed 11/01/02 (paper no. 35) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

**Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

11) Claims 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 72, 75, 76, 78, 80-91, 93, 123-128 and 130 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 45, 47, 56, 62, 75, 76, 78, 87 and 93 are vague and indefinite in the recitation "amino acids ..... of SEQ ID NO: 5 ...." without reciting that SEQ ID NO: 5 represents an amino acid sequence. For clarity and in order to distinctly claim the subject matter of the instant invention, it is suggested that Applicants replace the recitation with --amino acids .... of the amino acid sequence, SEQ ID NO: 5 ....--.

(b) Claim 72 is vague and indefinite in the recitation 'antigen comprising SEQ ID NO: 5' without reciting that SEQ ID NO: 5 represents an amino acid sequence. For clarity and in order to distinctly claim the subject matter of the instant invention, it is suggested that Applicants replace the recitation with --antigen comprising the amino acid sequence of SEQ ID NO: 5--.

(c) Claims 81-83 is vague and indefinite in the recitation 'amino acids from SEQ ID NO: 5' without reciting that SEQ ID NO: 5 represents an amino acid sequence. For clarity and in order to distinctly claim the subject matter of the instant invention, it is suggested that Applicants replace the recitation --amino acids from the amino acid sequence of SEQ ID NO: 5--.

(d) Analogous criticism and rejection applies to claims 89, 123-125 and 130.

(e) Claims 45, 54, 62, 72, 75, 78, 81 and 126 are vague and indefinite in the use of the abbreviated recitation: "CAI" in the claim language. It is suggested that the abbreviation be recited as a full terminology at first occurrence in the base claim, with its abbreviated recitation retained in parentheses.

(f) Claims 45, 54, 62, 75 and 78 are confusing and/or incorrect in the recitation "polypeptide ... comprises at least ten contiguous amino acids of SEQ ID NO: 5 .... includes ... SEQ ID NO: 9". These claims, for example, include a decapeptide or a dodecapeptide of SEQ ID NO: 5. However, such a decapeptide or dodecapeptide cannot include SEQ ID NO: 9, because SEQ ID NO: 9 is longer than ten amino acids.

(g) Claims 84, 86, 89 and 126 are vague and indefinite in the recitation "immunogenic derivative", because it is unclear what is encompassed in the recitation 'derivative'. What constitutes a derivative, and how much of the polypeptide's original structure has to be retained such that the resulting polypeptide can be considered as a 'derivative', is not clear. The metes and bounds of the structure encompassed in the limitation 'derivative' is indeterminate.

(h) Claims 84-86, 89 and 126 lack proper antecedent basis for the recitation: "of *Helicobacter pylori* CAI antigen". These claims or the claims that they depend from already include the recitation or an earlier recitation of '*Helicobacter pylori* CAI antigen' and therefore, the later limitations should have the antecedence; --the-- or --said--.

(i) Claim 89 is vague and indefinite in the recitation "derivative .... immunogenically identifiable with the protein encoded by SEQ ID NO: 5", because it is unclear what is encompassed

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in this limitation. What does 'immunogenic identifiability' involves is unclear. What characteristics a 'derivative' should have in order to be 'immunogenically identifiable' with the 'protein encoded by SEQ ID NO: 5' is not clear.

(j) Claim 89 is vague, indefinite and incorrect in the recitation: "the protein encoded by SEQ ID NO: 5", because SEQ ID NO: 5 is identified in claim 40 as an amino acid sequence and therefore, it is unclear how an amino acid sequence can 'encode' a protein.

(k) Claim 89 is further confusing in the recitation "the protein encoded by SEQ ID NO: 5", because claim 40, for example, identifies SEQ ID NO: 5 as the amino acid sequence of a 'polypeptide'. It is unclear how a 'protein' differs from 'polypeptide'.

(l) Claim 90 is vague and indefinite in the recitation "do not substantially affect the functional aspects of said antigen", because the metes and bounds of 'functional aspects' is indeterminate. What aspects of the antigen qualify as 'functional aspects' and what functions are encompassed within the limitation are not understood. What is intended by the phrase "which do not substantially affect" is not clear.

(m) Claims 45, 54, 57, 62, 63, 70, 75, 78, 81 and claim 89 are confusing in the recitation "immunologically identifiable" and "immunogenically identifiable" respectively, because it is unclear how the two limitations differ from one another.

(n) Claims 57, 59, 68, 80, 88, 91, 127 and 128, which depend directly or indirectly, from one of the base claims identified above, are also rejected as being indefinite because of the vagueness or indefiniteness identified above in the base claim.

#### **Rejection(s) under 35 U.S.C. § 112, First Paragraph**

**12)** Claims 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 75, 76, 78, 80-91 and 93 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 45, 54, 57, 62, 63, 70, 75, 78 and 81, as amended, include the new limitation: "immunologically identifiable by an antibody which reacts specifically with *Helicobacter pylori* CAI antigen" or "cytotoxin" or "heat shock protein". Applicants state that this limitation is supported in

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the specification at Figure 4 and on page 14, lines 31-34; and page 40, line 16 through page 41, line 17. Figure 4 does identify SEQ ID NO: 9, SEQ ID NO: 10 and six contiguous asparagine residues within SEQ ID NO: 5. However, the rest of the parts of the specification pointed to by Applicants does not provide support for a purified or recombinant polypeptide comprising 'at least ten contiguous amino acids' of SEQ ID NO: 5 that includes 'SEQ ID NO: 9, SEQ ID NO: 10 or six contiguous asparagine residues' which is "immunologically identifiable by an antibody which reacts specifically with *Helicobacter pylori* CAI antigen", as recited. For instance, a decapeptide of SEQ ID NO: 5 that includes the NNNNNN sequence, or the EPIYA sequence is not described within the instant specification as being 'immunologically identifiable by an antibody which reacts specifically with *Helicobacter pylori* CAI antigen'. Similarly, there is no descriptive support in the instant specification for a ten-amino acid long *Helicobacter pylori* cytotoxin or heat shock protein that is 'immunologically identifiable by an antibody which reacts specifically with *Helicobacter pylori*' heat shock protein or cytotoxin. Therefore, the limitation in the claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or invited to point to specific pages and line numbers in the specification where support for such a recitation can be found.

13) Claims 93 and 130 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 93 and 130 include the new limitation: "at least five contiguous amino acids from amino acids 707-937 of SEQ ID NO: 5" and "at least fifteen contiguous nucleotides of nucleotide positions 2772-3466 of SEQ ID NO: 4" respectively. However, there appears to be no support in the instant specification for these limitations. Applicants have not pointed to a part of the specification that provides descriptive support for these limitations. Therefore, the limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New

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matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or invited to point to specific pages and line numbers in the specification where support for such recitations can be found.

14) Claims 57, 59, 63, 70 and 80 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Instant claims claim a polypeptide product comprising an at least 10 amino acid-long CAI polypeptide of SEQ ID NO: 5 along with an at least ten contiguous amino acid-long second polypeptide of a *H. pylori* cytotoxin or *H. pylori* heat shock protein (hsp). These at least ten-mer polypeptides do not exist independent of their function, but are required to be "immunologically identifiable by an antibody which reacts 'specifically' with the CT or hsp antigen from any strain of *Helicobacter pylori*. However, claims that recite a 'second polypeptide' do not identify the CT, hsp, or the 'at least ten contiguous amino acids' thereof by a specific amino acid sequence identifier, i.e., a SEQ ID number. The instant specification does not precisely identify 'at least ten contiguous amino acids' of CT or hsp that are "immunologically identifiable by an antibody which antibody reacts 'specifically' with a CT or hsp from any strain of *Helicobacter pylori*. In order for one of skill in the art to produce the instantly claimed at least 10-mer polypeptide product which is 'immunologically identifiable by an antibody which reacts specifically' with *H. pylori* cytotoxin or *H. pylori* hsp, one must be able to choose 'at least ten contiguous amino acids' from an amino acid sequence having a specific SEQ ID number that represents *H. pylori* cytotoxin or *H. pylori* hsp. In the absence of recitation of a specific SEQ ID number in the claims, one skilled in the art would not know which cytotoxin or heat shock protein of which strain of *H. pylori* should be chosen to produce the claimed product. This is especially critical given the antigenic variability or heterogeneity among the polypeptides produced by *H. pylori*. Furthermore, in order to be immunologically identifiable with an antibody that is 'specific' to *Helicobacter pylori* CT, CAI or



hsp, the claimed CAI, CT or hsp polypeptide must be unique to *Helicobacter pylori* CT, CAI or hsp and must not be shared by other microbial or non-microbial antigens. A review of the specification shows that Applicants have not described such polypeptide fragments that specifically react with an antibody specific to *Helicobacter pylori* CT, CAI or hsp. The art, for example, indicates that the instantly recited SEQ ID NO: 10 contained within SEQ ID NO: 5 is not specific or unique to *Helicobacter pylori* CAI antigen, but is shared by several non-*Helicobacter pylori* proteins. For instance, Peterson *et al.* taught a purified recombinant non-*Helicobacter pylori* polypeptide comprising the amino acid sequence of SEQ ID N: 10 (see the art rejection below). Similarly, six contiguous asparagine residues are ubiquitously comprised in several non-*Helicobacter pylori* polypeptides, including the commercially available polyasparagines. With regard to the second polypeptide, *Helicobacter pylori* hsp, the art recognizes and the instant specification describes that *Helicobacter pylori* hsp is highly homologous with the HSP of all living organisms, including animals (see pages 7 and 60). This means that the epitopes of *Helicobacter pylori* hsp are not specific to *Helicobacter pylori*, but are immunologically identifiable by an autoimmune antibody that reacts specifically with a host heat shock protein. The specification also describes variability in *Helicobacter pylori* hsp antigen recognition by antisera, thus suggesting antigenic heterogeneity among hsp polypeptides produced by different strains of *Helicobacter pylori*. See lines 5-13 of page 57 of the instant specification. Further added to this is the conformational complexity of the epitopes of *Helicobacter pylori* CT (see abstract of Manetti *et al. Infect. Immun.* 63: 4476-4480, November 1995, already of record). Given these, one of skill in the art cannot produce immunologically identifiable at least ten-mer CT or hsp polypeptides that are *Helicobacter pylori*-specific without the recitation of a specific SEQ ID number in the claims for CT and hsp.

Because of the absence of a SEQ ID number in the instant claims for CT and hsp, at least 10-mer polypeptides of any CT or hsp from any strain of *H. pylori* are encompassed in the scope of the claims. However, the instant specification discloses only one full length CT or hsp polypeptide species from one particular strain of *H. pylori*, CCUG 17874 (see page 48; and Figures 2 and 5) and fails to identify at least 10-mer fragments from this one CT or HSP polypeptide species that are specifically reactive with an anti-CT or anti-hsp antibody. The claimed CT, hsp, or at least 10-mer CT or hsp polypeptide genus encompasses undisclosed CT and hsp species including those yet to be

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discovered. The precise structure or relevant identifying characteristics of each at least 10-mer CT or hsp polypeptide as claimed, wherein the polypeptide fragment has the recited functional property, can only be determined empirically by actually making every polypeptide that is encompassed in the claims and testing them. However, the structural composition described for one full length CT or hsp species from one strain of *H. pylori* does not constitute adequate description for the whole genus of the polypeptide or fragment polypeptide claimed. In view of the antigenic variability or heterogeneity disclosed within the instant specification, the art-disclosed epitopic non-specificity, and the level of knowledge and skill in the art, one skilled in the art would not recognize from the instant disclosure that Applicants were in possession of the genus of CT or hsp polypeptide as claimed. The *Written Description Guidelines* state:

There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between the structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function.

The description provided for in the instant specification is insufficient for the various claimed at least ten-mer polypeptide species. The claimed polypeptide species have specific biological properties dictated by the structure of the polypeptide and the corresponding structure of the structural gene sequence which encodes it. There has to be some nexus between the structure of the polypeptide sequence and the function of such a polypeptide. However, the function cannot be predicted from the modification or truncation of the structure of the recited or unrecited polypeptide. Applicants have not shown that modification of one reference polypeptide, SEQ ID NO: 5, or the generically recited CT or hsp, would automatically predict the production of ten-mer CAI, CT or hsp polypeptides of *H. pylori* as claimed. The specification fails to teach the structure or relevant identifying characteristics of a representative number of at least 10-mer polypeptide species from a representative number of species of *H. pylori* CAI, CT or hsp polypeptides, sufficient to allow one skilled in the art to determine that inventors had possession of the invention as claimed. With the exception of a full length isolated polypeptide of the amino acid sequence, SEQ ID NO: 5, a skilled artisan cannot envision the detailed chemical structure of the at least ten-mer polypeptide sequences encompassed by the claims. Regardless of the complexity or simplicity of the method of isolation, conception cannot be achieved until reduction to practice has occurred. Adequate written

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description requires more than a mere statement that its is a part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. See Written Description Requirement, *Federal Register*, vol. 66, no. 4, Notices, pp. 1099-1111, 05 January 2001). Since which at least 10-mer or 15-mer polypeptide fragment would retain *H. pylori* specific immunological identifiability is neither disclosed, nor could be predicted, and since the precise epitopes on the CT or hsp polypeptide responsible for immunological reactivity with a specific antibody are not known or identified, one of ordinary skill would be forced into experimentation that is undue.

**Rejection(s) under 35 U.S.C. § 102**

15) Claim 81 is rejected under 35 U.S.C. § 102(e) as being anticipated by Keene (US 5,541,291).

Keene disclosed an isolated polypeptide comprising at least five contiguous amino acids, Leu Lys Glu Arg Gln Glu Ala Glu Lys (LKERQEAEK), which shows 100% sequence identity with the instantly claimed polypeptide comprising at least 5 contiguous amino acids from SEQ ID NO: 5. See the claim; and the attached sequence search report. Although Keene is silent about the ability of the polypeptide to be immunologically identifiable by an antibody which reacts specifically with *Helicobacter pylori* CAI antigen, the prior art polypeptide is viewed as the same as Applicants' polypeptide. The Office's position that Keene's polypeptide is the same as Applicants' polypeptide is based upon the fact that every characteristic overlapping in the Keene's and Applicants' disclosure are the same. In spite of the fact that Keene fails to teach the recited functional characteristic of the Applicants' polypeptide, there is sufficient overlap to reasonably conclude that Keene's polypeptide is one and the same as the Applicants' polypeptide. Since the prior art polypeptide is structurally the same as the polypeptide recited in the instant claims, it is expected to be immunologically identifiable by an antibody which reacts specifically with *Helicobacter pylori* CAI antigen. The property of immunological identifiability by an antibody which reacts specifically with *Helicobacter pylori* CAI antigen is viewed as an inherent property of the polypeptide of Keene.

Claim 81 is anticipated by Keene.

16) Claim 139 is rejected under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, abstract).

Peterson *et al.* taught a purified recombinant polypeptide comprising the amino acid sequence

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of SEQ ID N: 10. See the attached sequence search report and abstract.

Claim 139 is anticipated by Peterson *et al.*

17) Claims 45, 47, 54, 56, 62, 68, 75, 76, 78, 81-86, 88-91, 93, 123-126, 128 and 130 are rejected under 35 U.S.C. § 102(e) as being anticipated by Cover *et al.* (US 5,403,924 - Applicants' IDS) ('924).

Cover *et al.* ('924) disclosed *H. pylori tagA* antigenic fragments (see abstract) or truncated *tagA* antigens that are at least about five amino acids-long and immunoreactive. The fragments are derived synthetically or recombinantly from the amino acid sequence of the antigen of SEQ ID NO: 2 (see Sequence Listing; paragraph bridging columns 3 and 4; and first two paragraphs in column 4). Immunogenically specific fragments are administered to an animal to induce an immunological response in the animal (see fourth full paragraph in column 4). The antigens include purified polypeptide fragments and are used, in immunogenically effective amounts, as vaccines along with a pharmaceutically acceptable carrier (see fifth full paragraph in column 3; and section 'Vaccines' in column 10). Thus, a method of bringing the polypeptide into association with a pharmaceutically acceptable carrier is disclosed. A sequence search performed in the Office showed that one of Cover's ('924) antigenic fragments has 100% sequence identity with an at least 100 amino acid-long fragment of the instantly claimed polypeptide of SEQ ID NO: 5. Cover *et al.* ('924) also taught a 859 amino acid-long polypeptide comprising several stretches of at least five, ten or fifteen contiguous amino acids including the instantly recited SEQ ID NO: 9 which falls in the region of amino acid residues 707-937 of SEQ ID NO: 5 (see the two attached amino acid sequence search reports). Cover *et al.* ('924) also taught a polypeptide encoded by at least fifteen contiguous nucleotides which fall in the region of nucleotide positions 2772-3466 of SEQ ID NO: 4 (see the attached nucleotide sequence search report). Cover *et al.* ('924) disclosed a polypeptide comprising at least five, ten or 15 contiguous amino acids encoded by SEQ ID NO: 4 and an immunogenic fragment or derivative thereof with one or more amino acid deletions, for example, of amino acids at positions beyond position 859, or having a conservative amino acid substitution, for example, K to R substitution at position 609 of SEQ ID NO: 5 (see the attached sequence search report).

Although Cover *et al.* ('924) are silent about the ability of their immunoreactive antigenic polypeptide fragments or derivatives to be immunologically identifiable by an antibody which reacts

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specifically with *Helicobacter pylori* CAI antigen, the prior art polypeptide is viewed as the same as the Applicants' polypeptide. That the contiguous stretches of amino acids taught by the prior art ('924) are long enough to be immunologically identifiable by an antibody specifically reactive with *H. pylori* CAI antigen is inherent from the teachings of Cover *et al.* ('924). The Office's position that Cover's ('924) polypeptide is the same as the Applicants' polypeptide is based upon the fact that every characteristic overlapping in the Cover's ('924) and Applicants' disclosure are the same. In spite of the fact that Cover *et al.* ('924) fail to expressly teach the functional characteristic of the Applicants' polypeptide, there is sufficient overlap to reasonably conclude that Cover's ('924) polypeptide is one and the same as the Applicants' polypeptide. Since the prior art polypeptide is structurally the same as the polypeptide recited in the instant claims, it is expected to be immunologically identifiable by an antibody which reacts specifically with *Helicobacter pylori* CAI antigen. The property of immunological identifiability by an antibody which reacts specifically with *Helicobacter pylori* CAI antigen is viewed as an inherent property inseparable from the polypeptide of Cover *et al.* ('924).

Claims 45, 47, 54, 56, 62, 68, 75, 76, 78, 81-86, 88-91, 93, 123-126, 128 and 130 are anticipated by Cover *et al.* ('924).

#### Remarks

18) Claims 45, 47, 54, 56, 57, 59, 62, 63, 68, 70, 72, 75, 76, 78, 80-91, 93, 123-128, 130 and 139 stand rejected. Claims 40 and 41 are allowable.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

20) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to

Serial Number: 09/360,685  
Art Unit: 1645

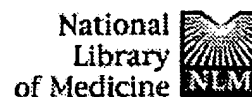
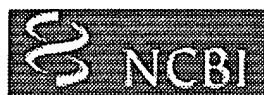
Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May, 2003

  
S. DEVI, PH.D.  
PRIMARY EXAMINER



PubMed	Nucleotide	Protein	Genome	Structure	PMC	Taxonomy	OMIM
Search	PubMed	<input type="button" value="for"/>					
Clear							
Limits Preview/Index History Clipboard De							
Display	Abstract	<input type="button" value="v"/>	Show: 20	<input type="button" value="v"/>	Sort	<input type="button" value="v"/>	Send to Text <input type="button" value="v"/>

☐ 1: Nature 1991 Dec 5;354(6352):369-73 Related Articles, Links

Entrez  
PubMed

## Structure and functional properties of human general transcription factor IIE.

Peterson MG, Inostroza J, Maxon ME, Flores O, Admon A, Reinberg D, Tjian R.

Howard Hughes Medical Institute, Department of Molecular and Cell Biology, University of California, Berkeley 94720.

PubMed  
Services

The general transcription factor IIE (TFIIE) is an essential component of the eukaryotic RNA polymerase II initiation complex. We have isolated human complementary DNA clones for both the subunits of TFIIE. Using purified recombinant proteins we find that both subunits are essential to form a stable preinitiation complex and to reconstitute basal-level and Sp1-activated transcription in vitro. Analysis of their predicted amino-acid sequences reveals several intriguing structural motifs that could provide insight into the role of TFIIE in transcription initiation.

PMID: 1956398 [PubMed - indexed for MEDLINE]

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SEQ ID NO: 4

RESULT 12  
US-08-053-614-1  
; Sequence 1, Application US/08053614  
; Patent No. 5403924  
; GENERAL INFORMATION:  
; APPLICANT: BLASER, TIMOTHY L.  
; APPLICANT: COVER, MARTIN J.  
; APPLICANT: TUMURU, MURALI K. R.  
; TITLE OF INVENTION: THE TAGA GENE AND METHODS FOR DETECTING  
; TITLE OF INVENTION: PREDISPOSITION TO PEPTIC ULCERATION  
; NUMBER OF SEQUENCES: 4  
; CORRESPONDENCE ADDRESS:  
; ADDRESSEE: NEEDLE & ROSENBERG, P.C.  
; STREET: 133 Carnegie Way, Suite 400  
; CITY: Atlanta  
; STATE: Georgia  
; COUNTRY: USA  
; ZIP: 30303  
; COMPUTER READABLE FORM:  
; MEDIUM TYPE: Floppy disk  
; COMPUTER: IBM PC compatible  
; OPERATING SYSTEM: PC-DOS/MS-DOS  
; SOFTWARE: Patentin Release #1.0, Version #1.25  
; CURRENT APPLICATION DATA:  
; APPLICATION NUMBER: US/08/053,614  
; FILING DATE: 19930426  
; CLASSIFICATION: 435  
; ATTORNEY/AGENT INFORMATION:  
; NAME: SPRATT, GWENDOLYN D.  
; REGISTRATION NUMBER: 36,016  
; REFERENCE/DOCKET NUMBER: 2200.009  
; TELECOMMUNICATION INFORMATION:  
; TELEPHONE: 404/688-9880  
; TELEFAX: 404/688-9880  
; INFORMATION FOR SEQ ID NO: 1:  
; SEQUENCE CHARACTERISTICS:  
; LENGTH: 3648 base pairs  
; TYPE: NUCLEIC ACID  
; STRANDEDNESS: double  
; TOPOLOGY: linear  
; MOLECULE TYPE: DNA (genomic)  
; ORIGINAL SOURCE:  
; ORGANISM: Helicobacter pylori  
; FEATURE:  
; NAME/KEY: CDS  
; LOCATION: 1072..3648  
; US-08-053-614-1  
  
Query Match 45.2%; Score 2679.4; DB 1; Length 3648;  
Best Local Similarity 93.2%; Pred. No. 0;  
Matches 2906; Conservative 0; Mismatches 186; Indels 25; Gaps 9;  
  
Qy 1 ctcctatttaagcaactccatagaccactaaagaaacttttttgaggctatcttga 60  
Db 548 CTCCTATTAGCAACTCCATAAACCACTAAAGAAACTTTTTTGTAGACTCTCTTGA 607  
Qy 61 atctgtcctattgattgttttccattttgttcccatgtgagctcttgatcacaac 120  
Db 608 ATCTGCTCTATTGATTTGTTTCCATTGTTTCCATGCGGATC-----ACAACGCTT 662  
Qy 121 gcttaattatatactataagcatg--acacacaaacaaactatttttagaagcgc 178

Db 663 AATTACAATACTACTATATAAGTAGGCACACACAAACCAACCATTTTGTAGACGC 722  
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Db 723 TTCATGCACCTACCTTGCTCTCAACCATTTCTCAACCAT-CTTTAGCGTTGCATTGAT 781  
Qy 237 tttctcaaaaagattcatttcttatttcttcttatttaagttcttcttctttagca 296  
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Qy 297 attttgttaattgtgggtaaaaatgtgaatcg-tcctagccttttagacgctgcaacga 355  
Db 842 ATTTTGTGTAATTTGGGTAAAAATGTGAATCGTTCTTCTAGCTTTTGTAGACGCTGCACGA 901  
Qy 356 tcgggcttttttcaatttaataatgatttaagaaaaaataaaatcgttgatattgt 415  
Db 902 TCGGACTTTTTTCAATATTATGCA-----AAAAATGCCAAATATTCTAAATATTGT 952  
Qy 416 tgtataatgagaattgtcaaaagacatgaattgactctc-aagcgtgtgagcgttttttag 474  
Db 953 GGTATAGTGATACGTTCAAAAGACACAGATTGCATCTACTCAAGTGTGTAGTAGTTTGTAG 1012  
Qy 475 cagcttttgacactacaagataccgtagatggtatgaactaggtatagtagtagagagaaca 534  
Db 1013 CGGTCTTTGATACCAATAAGATACCGTAGGTATGAAACAGTAGGTATAG-TAGGAGAAACA 1071  
Qy 535 atgactaaagaaacatttgaccacaaacacacacacacacacacacacacacacacacac 594  
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Qy 655 cctgatcaaaaac 714  
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Qy 955 ttatgaaaaatatacacaacccccctatctcttgatgataaaagagaaaagcggagttttg 1014  
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Db 1732 TCTTCTGATGTCAAGAGCAATCAATCAAGAACCACCTTCCTCATGTCTCAACACAGATATA 1791



Seq ID No: 4 (could)

493 22

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Db 1852 AGGGTAATTTTCTAAATTCACCTTGGCGATATGGAATGTAGATGTGAGGCGTC 1911  
QY 1375 gctgacattgatcccaattacaagttcaatcaattattgattcaccaataacgcctgtct 1434  
Db 1912 GCCACATGATGCCAATTAACAGTTCAATCAATTATGATTCACAAATACACTCTGTCT 1971  
QY 1435 tctgtttaaaggggagtcataatgacatagaaacctgaataaaggcttcttgatggg 1494  
Db 1972 TCTGTGTAAATGGGGAGTCATGATGTCATAGAACCTGAAAGATTTTCATTTATGATGCG 2031  
QY 1495 ggaatgggtgctgagctagtcagtcattggaagccacccgttggttataaagaccaa 1554  
Db 2032 GGCANTGGTGGTTTGGAGCCAGCAGATTTGGAACGCCACCCTTGGTTATTAAGACCAA 2091  
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Gaps 0;  
FS 758  
II  
fs 778

RESULT 13  
AAW03715  
ID AAW03715 standard; protein; 227 AA.  
XX  
AC AAW03715;  
XX  
DT 12-MAR-1997 (first entry)  
XX  
DE Human autoantigen U2-RNP.  
XX  
KW Autoimmune disease; ribonucleoprotein; ribosome; autoantigen; U2bp;  
KW severe polymyositis-scleroderma overlap syndrome.  
XX  
OS Homo sapiens.  
XX  
PN US5541291-A.  
XX  
PD 30-JUL-1996.  
XX  
PF 31-DEC-1984; 84US-0687908.  
XX  
PR 27-MAY-1987; 87US-0054871.  
PR 31-DEC-1984; 84US-0687908.  
XX  
PA (UYDU-) UNIV DUKE.  
XX  
PI Keene JD;  
XX  
DR WPI; 1996-362015/36.  
XX  
PT Auto-antigen U2-RNP, associated with severe polymyositis-scleroderma  
PT overlap syndrome - useful for diagnosis and treatment of autoimmune  
PT diseases  
XX  
PS Claim 1; Column 26; 21pp; English.  
XX  
CC The U2-RNP antigen is relatively rare among autoimmune patients but  
CC is frequently associated with a severe polymyositis-scleroderma  
CC overlap syndrome. The antigen was cloned using serum from one  
CC patient and a human liver cDNA library. U2-RNP is reactive with

CC approximately 5-10% of tested sera.  
XX  
SQ Sequence 227 AA;

Query Match 0.8%; Score 9; DB 17; Length 227;  
Best Local Similarity 100.0%; Pred. No. 3.7;  
Matches 9; Conservative 0; Mismatches 0; Indels 0; Gaps 0;  
QY 190 LKEROEAEK 198  
Db 124 lkerqeak 132

SEQ ID NO.5

SEQ 9

RESULT 15  
AAB57048  
ID AAB57048 stan  
XX  
AC AAB57048;  
XX  
DT 13-MAR-2001  
XX  
DE Human prostat.  
XX

SEQ ID NO. 5  
oligo

RESULT 6  
AAR72594  
ID AAR72594 standard; Protein; 859 AA.  
XX  
AC AAR72594;  
XX  
DT 29-SEP-1995 (first entry)  
XX  
DE H. pylori tagA antigen (truncated).  
XX  
KW TagA; antigen; ulcer; diagnosis; vaccine.  
XX  
OS Helicobacter pylori.  
XX  
PN US5403924-A.  
XX  
PD 04-APR-1995.  
XX  
PF 13-OCT-1992; 92US-0959940.  
XX  
PR 13-OCT-1992; 92US-0959940.  
PR 26-APR-1993; 93US-0053614.  
XX  
PA (UYVA-) UNIV VANDERBILT.  
XX  
PI Blaser MJ, Cover TL, Tummuru MKR;  
XX  
DR WPI: 1995-146855/19.  
DR N-PSDB; AAQ86728.  
XX  
PT New nucleic acid encoding tagA antigen of Helicobacter pylori  
used to detect predisposition to peptic ulceration and to produce  
protein for use in vaccines, diagnosis etc.  
XX  
PS Disclosure; Column 37-46; 30pp; English.

XX  
CC The full-length sequence of the tagA gene of H. pylori 84-183 (ATCC  
CC 53726) was obtained from overlapping clones isolated from genomic  
CC libraries. The gene encoded a 1181-amino acid TagA antigen  
CC protein (AAR72593) and a truncated antigen (AAR72594).  
XX  
SQ Sequence 859 AA;

Query Match 8.7%; Score 100; DB 16; Length 859;  
Best Local Similarity 100.0%; Pred. No. 5e-88;  
Matches 100; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 MTNETIDQOPQTEAAFNPQOFINNLOQVAFKVDNAVASYDPDQKPIVDKNDNRDRQAFEG 60  
DB 1 mtnetidqqpqttaafnpqqfnnlqvafkvdnavasydpdqkpivdkndrdarqafeg 60  
QY 61 ISQLREEYSNKAIKNPTKKNOYFSDPFINKSNDLINKDNL 100  
DB 61 isqlreecysnkaiknptkknqyfsdfinksndlinkdnl 100

ID AAR72594 standard; Prote 59 AA.

XX AAR72594;

XX 29-SEP-1995 (first entry)

XX H. pylori tagA antigen (truncated).

XX TagA; antigen; ulcer; diagnosis; vaccine.

XX Helicobacter pylori.

XX US5403924:A.

XX 04-APR-1995.

XX 13-OCT-1992; 92US-0959940.

XX 13-OCT-1992; 92US-0959940.

XX 26-APR-1993; 93US-0053614.

XX (UYVA-) UNIV VANDERBILT.

XX

PI Blaser MJ, Cover TL, Tummuru MKR;

XX WPI: 1995-146855/19.

XX N-PSDB; AAQ86728.

XX New nucleic acid encoding tag A antigen of Helicobacter pylori -  
PT used to detect predisposition to peptic ulceration and to produce  
PT protein for use in vaccines, diagnosis etc.

XX Disclosure; Column 37-46; 30pp; English.

XX The full-length sequence of the tagA gene of H. pylori 84-183 (ATCC  
CC 53726) was obtained from overlapping clones isolated from genomic  
CC libraries. The gene encoded a 1181-amino acid TagA antigen  
CC protein (AAR72593) and a truncated antigen (AAR72594).

XX Sequence 859 AA;

SQ

Query Match 69.1%; Score 4056.5; DB 16; Length 859;  
Best Local Similarity 92.7%; Pred. No. 1.7e-201;  
Matches 796; Conservative 24; Mismatches 38; Indels 1; Gaps 1;

Qy 1 MTNETIDQQPTEAAFPQQFINNLQVAFKVDNAVASYPDQKPIVDKNDNRDNRQAFEG 60

Db 1 mtnetidqqpqttaafnpqqfinnlqvafkvdnavasydpdqkpivdkndrdrnrqafeg 60

Qy 61 ISQLREEYSNKAIKNPTKKNQYFSDPFINKSNDLINKDNLIDVESSTKSFKGQDQRYRIF 120

Db 61 isqlreeysnkaiknptkknqyfsdpfinksndlinkdnlivesstksfkfgdqdryrif 120

Qy 121 TSWVSHQNDPSKINTRSIRNFMENI IOPIIDDDKEAEFLKSAKQSFAGIIGNQIRTDQ 180

Db 121 tswvshqndpskintrsirnfmehitqppipddkeae flksakqsfagiignqirt dq 180

Qy 181 KFMGVFDES LKERQEA EKNGEPTGGDWLDIFLSFIFDKKQSSDVKEA INQEPVPHVQPD I 240

Db 181 kfmgvfdeslkerqeaeknggptggdwldiflsfifdkkqssdvkeainqep lphvqpdi 240

Qy 241 ATTTD I QGLPPEARDILDERGNFSKFTLGDMEMLDVEGVADIDPNYKFNQLLHNNALS 300

Db 241 atstthiqglppesrdildergnfskftlgdmemldvegadm pnykfnqllihntls 300

Qy 301 SVLMGSHNGIEPEKVSLLYGGNGGPGARHWDNATVGYKDQGGNNVATI INVHMKNKSGGLV 360

Db 301 svlmgshdgiepekvsllyagnggfgakhdwnatvgykdqggnnvatiinvhmknsgglv 360

Qy 361 IAGGEGKINNPSFYLYKEDQLTGSQRALSQEEIQNKIDFMEFLAQNNAKLDNLSEKEKEK 420

Db 361 iagggekinnpsfylykedqltgsqralsqeeiqnkidfme flaqnnakldslsekekek 420

Qy 421 RITEIKDFQKDSKAYIDALGNDRIFAVSKKDTKHSALITEFGNGDISYTIKDYCKKADKA 480

Db 421 rneikdfqkds kpyldalgn driafvskkdpkhsalitefngkdisytlkv m gkqika 480

Qy 481 LDREKNVT LQGLKHDGVMFVDYSNFKYTNA SKNPNKGVGTNGVSHLEVGFENKVAIFNL 540

Db 481 ldreknvtlqgnlkhdgvmfvnysnfkytnaskspnkgvgv tngvshleagfsvkvavnl 540

Qy 541 PDLNLAITSFVRRNIEDKLTTKGLSPQEA NKLIKDFLSSNKELVGKTLNPNKAVADAKN 600

Db 541 pdlnlaitsvrrndledklia kglspqean klykdf lssnk elvgkalnfnkavaeakn 600

Qy 601 TQNYDEVKKAQKDLKSLRKHLEKEVEKKLESKSGNKNKMEAKAQANSOKDEIFALIN 660

Db 601 tnydevkra qkdlkslkrhlekdvaknlesksgnknkmeakaqansqkdeifalin 660

Qy 661 EANRDARAIAYAQN LKGIKRELSDKLENVNKNLKD FDKSFDEFKNGKNKDFSKAEETLK 720

Db 661 eanrdaraiayaqn lkgikrelsdkleninkndkdfsksf defkngknkdfskaeetlk 720

Qy 721 ALKGSVKDLGINPEWISKVENLNAALNEFKNGKNKDFSKVTOAKSDLENSVKDVIINQKV 780

Db 721 alkgsvkdlginpewiskvenlnaalnefkngknkdfskvt oaksdqensikdvliinqki 780

Qy 781 TDKVDNLNQAVSVAKATGDFSRVEQALADLKNFSKEQLAQQAQKNESLNARKKSEIYQSV 840

Db 781 tdkvdelnqavsvakiacd fsgveqaladlknfskeqlaqqaqknesfnv-gkselyqsv 839

Qy 841 KNGVNGTLVGNLSQAEAT 859

Db 840 kngvngtlvnglsgleat 858

RESULT 7

S29291

transcription factor IIE 56K chain - human

C;Species: Homo sapiens (man)

C;Date: 22-Nov-1993 #sequence\_revision 10-Nov-1995 #text\_change 01-Dec-2000

C;Accession: S29291; S29319

R;Peterson, M.G.; Inostroza, J.; Maxon, M.E.; Flores, O.; Admon, A.; Reinberg, D.; Tj Nature 354, 369-373, 1991

A;Title: Structure and functional properties of human general transcription factor II

A;Reference number: S29291; MUID:92065976; PMID:1956398

A;Accession: S29291

A;Status: preliminary

A;Molecule type: mRNA

A;Residues: 1-439 <PET>

A;Cross-references: GB:S67859; NID:g239577; PIDN:AAB20413.1; PID:g239578

R;Ohkuma, Y.; Sumimoto, H.; Hoffmann, A.; Shimasaki, S.; Horikoshi, M.; Roeder, R.G. Nature 354, 398-401, 1991

A;Title: Structural motifs and potential sigma homologies in the large subunit of hum

A;Reference number: S29319; MUID:92065982; PMID:1956403

A;Accession: S29319

A;Status: preliminary

A;Molecule type: mRNA

A;Residues: 1-351,'D',353-439 <OHK>

A;Cross-references: EMBL:X63468; NID:g37067; PIDN:CAA45068.1; PID:g37068

C;Keywords: transcription regulation

Query Match 100.0%; Score 27; DB 2; Length 439;

Best Local Similarity 100.0%; Pred. No. 1.3e+02;

Matches 5; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 EPIYA 5

|||||

Db 185 EPIYA 189

SEE ID NO. 10.